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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/826,522	04/16/2004	Geert Plactinck	D0590.70011US02	2890
23628 7590 12/07/2007 WOLF GREENFIELD & SACKS, P.C. 600 ATLANTIC AVENUE BOSTON, MA 02210-2206			EXAMINER SHIN, DANA H	
			ART UNIT 1635	PAPER NUMBER
			MAIL DATE 12/07/2007	DELIVERY MODE PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/826,522	PLAETINCK ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Dana Shin	1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 01 November 2007.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 30-41, 70-74 and 80-83 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 30-41, 70-74 and 80-83 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 16 April 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on November 1, 2007 has been entered.

### ***Status of Claims***

Currently, claims 30-41, 70-74, and 80-83 are pending and under examination on the merits.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

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Claims 30-40, 70-74, and 80-83 are rejected under 35 U.S.C. 102(a) as being anticipated by Fire et al. (WO 99/32619 A1).

The claims are drawn to a micro-organism comprising an expression vector having two T7 promoters flanking a DNA sequence, wherein the promoters produce double-stranded RNA in the micro-organism, wherein the micro-organism is *C. elegans*, *E. coli* bacterium, a parasitic nematode, a plant, and a yeast cell, wherein the promoters are tissue-specific promoters, root-specific promoters instead of the T7 promoters.

Fire et al. teach *C. elegans* comprising an expression vector having two T7 promoters flanking a DNA sequence, wherein the promoters produce double-stranded RNA in the *C. elegans*. See Figures 5A-5C. They teach that the micro-organism comprising the expression vector can be any organism including plant, animal, protozoan, virus, *E. coli*, yeast, and parasitic nematode (pages 7, 12, 26). They teach that the promoters that mediate transcription of the double-stranded RNA in the micro-organism can be tissue-specific, and they teach that root-specific promoters can be used to transcribe the RNA in a plant (pages 13, 17-18). See also claims 36-38. Accordingly, all claim limitations are taught by Fire et al.

Claims 30-40, 70-74, and 80-83 are rejected under 35 U.S.C. 102(e) as being anticipated by Fire et al. (US 6,506,559 B1, also applicant's citation).

The claims are described above.

Fire et al. teach *C. elegans* comprising an expression vector having two T7 promoters flanking a DNA sequence, wherein the promoters produce double-stranded RNA in the *C. elegans*. See Figures 5A-5C. They teach that the organism can be a plant, animal, virus, *E. coli*,

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yeast, a parasitic nematode instead of the exemplified *C. elegans*. See columns 8-9, 11-12. They also teach that the promoters can be tissue-specific promoters (e.g., root-specific promoters) in place of the two T7 promoters. See columns 11 and 17. Accordingly, all claim limitations are taught by Fire et al.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 30-41, 70-74, and 80-83 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fire et al. (WO 99/32619) or Fire et al. (US 6,506,559 B1) as applied to claims 30-39, 70-74, and 80-83 above, further in view of Talkad et al. (*Journal of Bacteriology*, 1978, 135:528-541).

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Both of the Fire et al. references teach micro-organisms comprising an expression vector having two T7 promoters flanking a DNA sequence, wherein the promoters produce double-stranded RNA in the organisms. They both teach that the micro-organism can be a bacterium whose strain is BL21/DE3. Neither of the Fire et al. references teaches that the bacterium is *E. coli* is an RNase III negative strain.

Talkad et al. teach *E. coli* strains that are deficient in RNase III. They teach that RNase III cleaves bacteriophage T7 RNAs as well as double-stranded RNAs.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to use the RNase III-deficient *E. coli* strain as the micro-organism carrying a double-stranded RNA and T7 promoters.

One of ordinary skill in the art would have been motivated to do so with a reasonable expectation of success because the use of RNase III-negative bacterial strain would prevent cleavage of T7 promoters and the double-stranded RNA molecule, as taught by Talkad et al. Since the RNase III-negative *E. coli* strain was known and available in the art at the time of the invention, and since replacing the BL21/DE3 *E. coli* strain with the RNase III-negative *E. coli* strain was within the technical grasp of one of ordinary skill in the art at the time of the invention, the claimed invention taken as a whole would have been *prima facie* obvious at the time of filing.

### ***Conclusion***

No claim is allowed.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dana Shin whose telephone number is 571-272-8008. The examiner can normally be reached on Monday through Friday, from 8am-4:30pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Douglas Schultz can be reached on 571-272-0763. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Dana Shin  
Examiner  
Art Unit 1635

/J. E. Angell/  
Primary Examiner  
Art Unit 1635